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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,599	10/23/2001	Lino Tavares	208.1002US	8566

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,599

Applicant(s)

TAVARES ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 22-25, 27-40, 42-44 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 22-25, 27-40, 42-44 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response filed 12/22/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-18, 22-25, 27-40, 42-44 and 47 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures and teachings of Ma et al (USPN 5,843,472 hereafter 472), Audett et al (USPN 5,879,701 hereafter 701). Claims 1-18 are drawn to a method of treating benign prostatic hypertrophy in a human patient by administering terazosin transdermally. The claims recite the proper dosage regimen for the transdermal administration. The remaining claims are drawn to the transdermal device used in the method of claims 1-18. The device comprises an impermeable yet flexible backing layer, and a removable release liner. The polymeric matrix is a pressure sensitive adhesive with a silicone substrate. The device contains solvents and other well-known components.

Ma et al discloses a transdermal device useful in the treatment of benign prostatic hypertrophy (BPH). The device delivers basic drugs such as tamsulosin transdermally in order to treat benign prostatic hypertrophy. The device comprises an impermeable flexible backing layer and a release liner. The device is a pressure sensitive adhesive with a polymeric matrix.

The matrix uses silicone as a polymeric carrier and contains various glycols. Solvents used for the device include ethanol, and oleic acid solvents (Abstract; col. 6, lin. 29 – col. 8, lin. 58; claims).

What the reference is lacking is a disclosure of terazosin as the active agent. Audett et al discloses a transdermal formulation and device comprising a polymeric matrix, an impermeable yet flexible backing layer, a release liner and terazosin as an active basic drug ingredient (Abstract; col. 5, lin. 50 – 60; col. 6, lin. 63 – col. 8, lin. 50; claims). Since the two compositions and devices contain similar if not identical components, and structures, and are used for similar purposes, it would have been obvious to a skilled artisan to substitute the terazosin of Audett into the delivery device of Ma.

The claims are drawn to specific release profiles and dosage regimens in order to treat the BPH. The references and their combination do not recite the identical treatment regimen, yet this determination would be within the level of ordinary skill in the art. The claims also are drawn to specific concentrations of the particular components. These concentrations too can be determined through routine experimentation, by a skilled artisan. The general combination of components is presented in the art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Further claims 7, 8, 17, 18, 23, 24 and 34 recite that the transdermal has a particular in vitro behavior as determined by a Valia-Chien. It is the position for the examiner that these limitations are irrelevant to the patentability of the device and methods of use. These properties would be inherent to any identical transdermal comprising similar concentration and proportions made from similar and/or identical components. These limitations do not impart patentability on the invention by simply recited the results of diagnostic test which can be preformed by a skilled artisan of ordinary skill. It is the position of the examiner that given the combination of references presented, a skilled artisan would attain similar if not identical in vitro results from the same test.

With regard to claims 39 and 40, which recite particular solvents, it is the position of the examiner that these limitations do not impart patentability on the invention. The mere selection of species is well within the level of skill in the art. Barring a showing of criticality and unexpected results with the particular solvents, the limitations are deemed non-critical to the patentability of the invention.

With this in mind a skilled artisan would have been motivated to combine the teachings and suggestions of the art. A skilled artisan would have been motivated to combine the terazosin suggested by Audett with the transdermal formula and device of Ma in order to treat benign prostatic hypertrophy. A skilled artisan would have been motivated to make this combination since both transdermal formulations and devices comprise similar components and were used for the delivery of drugs and for the treatment of similar ailments. From this combination a skilled

artisan would be able to modify and optimize the concentrations of the active components in order to better deliver the pharmaceutical agents. A skilled artisan would be able to optimize the release and permeation of the drugs in to the skin. A skilled artisan would have expected from the combination transdermal device useful in the treatment of benign prostatic hypertrophy.

Response to Arguments

2. Applicant's arguments filed 12/22/03 have been fully considered but they are not persuasive. Applicant argues that:

- a. The art combination does not disclose a transdermal with a mean relative release rate recited in claim 1, and therefore does not obviate the invention.

Regarding this argument, it is the position of the examiner that such limitations recite optimized results of a similar invention. The combination of Ma and Audett are used within the same field of endeavor and contain identical components, namely a polymeric matrix, flexible backing and terazosin as the benign prostatic hypertrophy-treating agent. The average flux of the active agent can depend from the concentration of the active, type, and concentration of any penetration enhancers included in the formulation. The flux thereby can be manipulated and optimized through routine experimentation well within the levels of ordinary skill in the art. Applicant is invited to provide evidence supporting the criticality of the flux limitation, in addition to any unexpected results obtained from the instant invention. Barring this showing of criticality and unexpected results, the claims will remain obviated by the prior art. The prior art combination discloses the structure, and intended use of the instant invention obviating the instant invention.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young


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